EXHIBIT JJ

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Clinical Laboratory Evaluation Program

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1. When is a New York State laboratory permit required?

A laboratory is defined in New York State Public Health Law, Article 5, Title IV, section 571 as a "facility for the microbiological, immunological, chemical, hematological, biophysical, cytological, pathological, genetic, or other examination of materials derived from the human body, or the purpose of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of a health condition or for identification purposes. Such examinations shall include procedures to determine, measure or otherwise describe the presence or absence of various substances, components or organisms in the human body". This means that any facility issuing patient-identified results, including facilities performing research, clinical trials, insurance testing, forensic toxicology or forensic/paternity identity testing, except as described below, must hold a permit from this program. Exceptions to this requirement are outlined in Article 5, Title IV, section 579 and include:

- a) Laboratories operated by the federal government;
- b) Laboratories operated by a licensed physician, osteopath, dentist or podiatrist who performs laboratory tests or procedures, personally or through his or her employees, solely as an adjunct to the treatment of his or her own patients (see question 2, When does a Physician Office Laboratory need a permit?);
- c) Any examination performed by a state or local government of materials derived from the human body for use in criminal identification or as evidence in a criminal proceeding or for investigative purposes, any test conducted pursuant to paragraph (c) of subdivision four of section eleven hundred ninety-four of the vehicle and traffic law and paragraph or subdivision four of section 25.24 of the parks, recreation and historic preservation law;
- d) Any examination performed by a state or local agency of materials derived from the body of an inmate, pretrial releasee, parolee, conditional releasee or probationer to

  (i) determine, measure or otherwise describe the presence or absence of any substance whose possession, ingestion or use is prohibited by law, the rules of the department of correctional services, the conditions of release established by the board of parole, the conditions of release established by a court or a local conditional release commission or the conditions of any

  ii) to determine whether there has been a violation thereof;
- e) Any examination performed by a coroner or medical examiner for the medical-legal investigation of a death.

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2. When does a Physician Office Laboratory need a laboratory permit?

Private physician office laboratories operated by individual practitioners or as part of a legally constituted, independently owned and managed partnership or group practice are exempt from New York State laboratory permit requirements as long as the tests performed are conducted by the providers or by their own employees, utilizing their own reagents and instrumentation, solely as an adjunct to the practice of medicine for their patients. Physicians or groups of physicians operating independently owned laboratories solely to perform testing on their own patients must obtain CLIA certification through the Division's Physician Office Laboratory Evaluation Program. Information on CLIA certification for physician office laboratories may be obtained by contacting (518) 485-5352. Physician laboratories which are set up as a joint venture of several practitioners, partnerships or practices and practices which are owned, managed and/or operated by managed care organizations, hospitals or consulting firms are not included within this exemption and must obtain a New York State laboratory permit or register as a Limited Testing Site, depending on the complexity level of the testing performed.

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3. How does a laboratory obtain a New York State laboratory permit?

In order to receive a permit, a laboratory must:

- a) Complete an application;
- b) Submit required fees;
- c) Designate a laboratory director and, if applicable, assistant directors with certificates of qualification (CQ) in all permit categories for whichthe laboratory has applied;
- d) Successfully participate in one proficiency testing (PT) event (except for Toxicology - Blood Lead and Cytogenetics) for all applied categories, subcategories and for all analytes for which New York State proficiency testing is offered. For the Toxicology - Blood Lead and Cytogenetics categories, the laboratory must participate satisfactorily in two consecutive test events.
- e) If requested, submit standard operating procedures and validation data for review and approval by the Program;
- f) Complete a successful on-site inspection;
- g) Submit an acceptable plan of correction for any deficiencies cited during the on-site inspection; and,
- h) As outlined in 10 NYCRR subpart 58-3.8, an out-of-state laboratory seeking a New York State permit shall pay an on-site survey fee, which shall consist of a transportation expense and a per diem expense.

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4. What does "PFI" mean?

Permanent Facility Identifier (PFI).

A PFI number is a unique identification number assigned to New York State permitted laboratories.

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5. How does a laboratory add a category to an existing permit?

The laboratory must submit either a written request signed by the laboratory director or a notification form provided by the Department. The laboratory must complete a successful on-site survey and participate in one proficiency test event, except for Toxicology - Blood Lead and Cytogenetics. For the Toxicology - Blood Lead and Cytogenetics categories, the laboratory must participate satisfactorily in two consecutive test events. If there is no New York State proficiency test available in that permit category, the approval will be based on the survey. See also, frequently asked question number 15. In addition, method validation and/or SOPM review by the Department may be required.

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6. What are the requirements for the addition of a new test or analyte to a permit category for which the laboratory is already approved?

Laboratories adding a new analyte must submit either a written request signed by the laboratory director or a notification form provided by the Department. Proficiency testing and an on-site survey are no longer required prior to the addition of an analyte to an existing permit category. If the analyte is subject New York State proficiency testing, the laboratory will be enrolled in the next regularly scheduled event. Assay method validation and SOPM for the new analyte will be reviewed during the next routine survey. In addition, method validation and/or SOPM review by the Department may be required if the assay is not FDA approved, the intended use has been modified or is an inhouse developed or "home-brew". See submission guidelines for details.

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7. What is the procedure for deleting a category or analyte from an existing permit?

The laboratory must submit either a written request signed by the laboratory director or a notification form provided by the Department. Notification of category/analyte deletion must reach the Department at least two weeks prior to a scheduled proficiency test event to avoid affecting test grading. Failure to notify the Department within the specified time frame my result in a score of zero.

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8. Does a New York State laboratory permit satisfy a laboratory's CLIA requirements?

In August 1995, the Centers for Medicare and Medicaid Services (CMS) formerly known as Health Care Finance Administration granted New York State CLIA exempt status. For permitted laboratories located within New York State, the CLEP survey and participation in the New York State proficiency testing program meets both state and federal regulatory requirements. For permitted facilities located outside New York State, participation in the New York State proficiency testing program may be used to satisfy a laboratory's CLIA proficiency testing requirement.

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9. What should a laboratory do if the owner is in negotiations to sell the laboratory?

The permit is void once the change in ownership occurs. Therefore, the Department must be

notified as soon as the change is anticipated. When the change in ownership becomes finalized, a formal notification form must be signed by both the new and old owners or their representatives, and submitted to the Department.

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10. What procedures should be followed when a laboratory is changing locations?

Laboratories must submit a notification form provided by the Department. The Public Health Law states that the laboratory permit is void upon a change in the laboratory's location. Therefore, the form must be submitted as far in advance as possible, with indication of the best estimate of the move date. If staff, instrumentation, and procedures remain the same, proficiency testing records from the old location will be transferred to the new location to ensure uninterrupted operation of the laboratory. If a laboratory changes location within the same street address, a new permit is not required; however the laboratory should notify the Department so that a surveyor can visit the new location.

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11. Must a laboratory hold a permit to perform "health fair" laboratory testing?

According to the Public Health Law, a permitted laboratory must perform all laboratory testing, and oversee testing done at health fairs. The laboratory must submit a request to hold a health fair prior to the event (a laboratory may apply for all planned health fairs at one time). Tests performed at a health fair must be appropriate for screening the general population, and ordered by a licensed physician who, if necessary, is available to interpret abnormal results.

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12. How long must proficiency test records be retained?

Proficiency Testing Standard 9 states that a laboratory shall maintain copies of all records, including copies of the PT report forms used by the laboratory to record results, for a minimum of two years from the date of the PT event for all categories except immunohematology, for which records must be retained five years.

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13. Do all permit categories offer a proficiency testing program?

Due to the specimen degradation over time, availability of certain analytes and matrix incompatibilities, proficiency testing is not available for all analytes or for all permit categories. Refer to the "Guide to Program Requirements and Services". The guide is available on this this website and is included in the initial laboratory permit application packages. Laboratories may contact the Clinical Laboratory Evaluation Program for a copy of this Program Guide.

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14. If the laboratory director is not available to sign the proficiency test results reporting form before the postmark deadline, what should the laboratory do?

If the laboratory director or the authorized assistant director is unavailable to review the test results and sign the report prior to the postmark deadline, the laboratory should retain a copy of the results report form and transmit the unsigned original, with a note of explanation, to the proficiency test section. The copy of the document should be signed by the director or authorized assistant director and forwarded to the Department within two working days of their return.

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15. Must a laboratory participate in a proficiency testing program for analytes not included in the New York State proficiency testing program?

Quality Assurance Standard 8 requires that a laboratory shall have a system for verifying the reliability and accuracy of test results twice each year for all tests not evaluated in the New York State proficiency testing program. This may be accomplished by one or more of the following: participation in manufacturer or federally approved proficiency test programs; performance of split-sample comparisons (patient and/or quality control samples); evaluation of clinical outcomes; blind testing of specimens with known results, or other equivalent system. For microscopic tests not included in a PT program, the laboratory supervisor may retest a random sample of specimens throughout the year while assessing all testing personnel. For tests such as KOH preparation and sedimentation rates, the laboratory may utilize duplicate testing performed by two different testing personnel. Laboratories unable to participate in a New York State proficiency test event as a graded participant are required to establish alternate means to verify the accuracy and precision of the test system for all ungraded analytes.

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16. When point-of-care testing is performed in a facility, who is responsible for monitoring that testing?

Quality Assurance Standard 1 states that the laboratory director is responsible for all testing performed within the facility, including all point-of-care testing. The laboratory director should establish institutional protocols for the use of point-of-care devices.

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17. Who can perform point-of-care testing?

Since the testing is performed under the laboratory's permit, the laboratory director is responsible for assuring that the personnel performing the tests are properly trained and that competency evaluations are performed at regular intervals as outlined in Quality Assurance Standard 4. Personnel requirements are defined in 10 NYCRR subpart 58-1.5.

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18. Is proficiency testing (PT) required for point-of-care testing?

The laboratory should run PT on the method or instrument used as the primary method for performing routine specimen testing at the time of the PT event. For example, if a laboratory uses a conventional analyzer and a Point of Care Testing (POCT) device, PT samples would not be tested on the POCT device. However, Quality Assurance Standard 15 states that if the laboratory does the same test using different methods or instruments, or does the same test at multiple test sites, it must have a system in place that evaluates and defines the relationship between test results at least two times a year. The laboratory may use split samples, quality control material or previously graded PT specimens to meet this requirement. The relationship need not show numeric equality of the results from the two test systems if there is an appropriate difference in reference ranges. The laboratory should predetermine the percentage of allowable difference between the two compared methods.

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19. Can the laboratory use the manufacturer's electronic controls instead of matrix (liquid) controls?

General Standard 3 states that unless otherwise specified in the New York State Laboratory Standards, electronic controls used in accordance with the manufacturer's recommendations are acceptable alternatives to matrix controls if:

- a) the test system is not defined by CMS as being of high complexity;
- b) a system is in place to monitor the entire analytical system;
- c) the laboratory first establishes, through documented studies, the stability of the instrument; and,
- d) matrix controls are run with each new lot number or shipment and at a frequency recommended by the device manufacturer.

Acceptable validation documentation would include matrix appropriate control data that shows method stability over several weeks.

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20. How often should the laboratory document the competency of testing personnel?

Quality Assurance Standard 4 states that the laboratory shall have a mechanism to evaluate employee competence; and,

- a) this shall include, but not be limited to, direct observations of routine test performance, including patient/donor preparation, if applicable, specimen handling, processing and testing; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; assessment of problem solving skills; and,
- b) the evaluation and documentation of the performance of individuals shall be conducted at least semiannually during the first year the individual tests specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting results, the individual's performance shall be

evaluated to include the use of the new test methodology or instrumentation.

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21. Who can order laboratory tests?

As specified in 10 NYCRR Subpart 58-1.7, laboratories may examine specimens only at the request of a licensed physician or other persons authorized by law to use laboratory findings in their practice or performance of official duties. Persons currently authorized by law to request the examination of specimens include:

- a) physicians licensed to practice medicine in the state in which they are located;
- b) dentists and podiatrists within the scope of their practice;
- c) chiropractors within the scope of their practice as determined by the Executive Secretary of the State Board of Chiropractic;
- d) physician's assistants and certified nurse midwives with authorization from a supervising physician;
- e) designees of the Commissioner or of other government operated public health agencies, including local health units, provided such examination is authorized as a necessary adjunct to a public health activity;
- f) police officers provided such examination is incident to arrest charges for alcohol or drug impairment;
- g) judges ordering paternity tests under the Family Court Act,
- h) judges ordering tests for evidentiary purposes for use in a proceeding under their jurisdiction; and,
- i) representatives of insurance companies, provided that tests are requested in conjunction with an application for insurance and ordered pursuant to a protocol established by the insurance company's medical director.

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22. Why can't test results be given directly to the patient?

As specified in 10 NYCRR Subpart 58-1.8, laboratory results may only be given to a physician, his or her agent, or other person authorized by law to use the results in the conduct of his or her practice or the fulfillment of official duties. The majority of laboratory test results must be placed in the context of the patient's condition, medical history and symptoms, by a trained professional. While many patients have the knowledge, experience and good judgement to properly evaluate test results, the data may cause some patients unnecessary confusion, anxiety and sometimes, alarm. Laboratories are required to release test results to the physician ordering the tests so that a full explanation may be provided at the time that the patient receives the test results. Results may be issued to patients with the written consent of the physician or other authorized person. The exception to the regulation is results for blood type and Rh type. Results from these tests may be provided in writing to the individual whose blood was tested without consent of the physician.

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23. How many samples must be tested to validate a new method or instrument?

The laboratory should evaluate as many specimens as are necessary to ensure that the new instrument or method is performing to the laboratory's anticipated performance criteria. All phases of the procedure should be evaluated. Validation material should encompass the full range of testing that the laboratory expects to perform on patient samples. The laboratory director should assist in determining the number of specimens to test and document acceptance of the data before the new method is implemented for patient testing.

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24. Why is a cover sheet documenting the director's approval of all procedures in a procedure manual not acceptable?

General Standard 26 states that each policy and procedure shall be signed and dated by the current laboratory director or director-designated assistant directors holding appropriate certificates of qualification. Director-designated means documented delegation of this specific responsibility. Each individual procedure requires a signature and review date. The laboratory may use a cover sheet if it contains a list of all procedures, their implementation dates, all revision dates, and the director's signature. An unmodified operator's manual provided by the manufacturer may be considered as one procedure, and approval may be noted by signing and dating entries in the table of contents.

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25. Is the use of a package insert acceptable as a written procedure in the standard operating procedure manual (SOPM)?

Guidance to General Standard 23 states that unmodified package inserts and operator's manuals provided by the manufacturer may be used as a procedure description in the SOPM. Textbooks or journals may be used as supplements, but should not be used in lieu of the SOPM.

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26. How long should a laboratory keep discontinued procedures?

General Standard 29 states that discontinued procedures are required to be kept on file for two years after the procedure has been discontinued, except for blood banking. Section 58-2.8(a)(9) requires discontinued procedures to be retained for at least seven years.

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27. What is the definition of a run?

A run is an interval within which the accuracy and precision of a testing system are expected to be stable, but cannot be greater than 24 hours or less than the frequency recommended by the manufacturer, except for HIV testing for which a run is defined as follows:

ELISA - each microtiter plate or tray of beads;
IFA - each slide;
Western blot - each set of strips.

Although a run may be defined as up to 24 hours, a laboratory that elects to perform all quality control at a fixed time (e.g., the start of the day shift) should demonstrate that the system is stable throughout the 24 hour period.

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28. Why is frequency for equipment maintenance not specified in the current Laboratory Standards?

Laboratories have been given the opportunity to determine the maintenance schedule that best suits their needs and equipment but, as a minimum, the manufacturer's requirements must be met. Many variances (total number of tests performed, reliability of the instrument, stability of the method, etc.) should be assessed when determining preventive maintenance protocols.

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29. What is meant by an "exact duplicate" copy of a final test report? Must a laboratory retain a paper copy of all test reports if reports are stored electronically?

Guidance to Laboratory Information Systems (LIS) Standard 7 states that an exact duplicate is an exact copy of the information sent to the individual requesting the test or using the test results, and includes the name and address of the laboratory performing the test. The format of the original need not be duplicated as long as the information is identical. The exact copy need not be maintained as paper, but may be retrieved from a computer system, microfilm or microfiche record, as long as it contains the exact information sent to the individual ordering the test or using the test results. For tests requiring an authorized signature containing personnel identifiers (e.g., pathology examinations), the exact duplicate must include the signatures and/or identifiers.

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30. Must a laboratory retain copies of corrected or amended reports?

Laboratory Information Systems (LIS) Standard 10 states that if test results have been amended:

- a) the LIS shall have a mechanism to ensure that the initial report is not obliterated and/or changed in any way, except to indicate that an amended report has been issued, and stating the reason(s) for the change(s) and the date(s) the report was changed; and,
- b) there shall be a mechanism to prevent the reporting of the initial test results again, unless clearly identified as such.

If the LIS is not capable of maintaining both the original and amended copy, the laboratory may keep a hard copy of the original report and maintain the corrected report in the computer.

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31. What is the procedure for requesting permission to submit a specimen to a

laboratory that does not hold a New York State permit?

Approval to submit specimens to laboratories which do not hold New York State permits will be granted if the required test is not provided by a permit holding laboratory.

It is the responsibility of the physician or other authorized party ordering the test to document that the patient or legal guardian has been informed that the laboratory performing the diagnostic testing does not hold a New York State laboratory permit. Department approval to refer a specimen to a non-permitted laboratory should not be considered as an endorsement of the laboratory's competence or a guarantee that the laboratory has complied with all relevant federal and/or State regulations.

Requests for approval to submit a specimen for testing to a laboratory which does not hold a State permit should be submitted, in writing, to:

For Genetic Tests:

Michele Caggana, Sc.D., FACMG
Genetic Testing Quality Assurance Program
Wadsworth Center
New York State Department of Health
PO Box 509
Albany, New York 12201-0509

Telephone: 518-474-6271
FAX: 518-486-2693

For all other tests:

Deirdre Astin/Beth Johansen/Michael Neal
Certification Unit
Clinical Laboratory Evaluation Program
Wadsworth Center
New York State Department of Health
PO Box 509
Albany, New York 12201-0509

Telephone: 518-485-5378
FAX: 518-485-5414

Requests must include the following information:

- 1. Patient name and medical record number or laboratory identification number;
- 2. Disease(s) involved;
- 3. Specimen type (e.g. blood, plasma, urine, etc.);
- 4. Test requested;
- 5. Reason/justification for request;
- 6. Name, address, telephone number, FAX number, and PFI (laboratories only) of the facility submitting the request; and,
- 7. Name, address, and telephone number of the non-permitted laboratory to which the specimen is being submitted for testing.

The Program will respond, in writing, to each request to use a non-permitted laboratory. If the request is rejected, the reason for denial will be explained in the Department's response.

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32. What is a Limited Service Laboratory?

The designation "Limited Service Laboratory" was established for facilities that perform only tests classified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as waived or provider-performed microscopy procedures (PPMP). These facilities include hospital extension clinics, nursing homes, home health care agencies, school/student health services, dialysis facilities, ambulatory surgery centers, county health departments, correctional facilities, ambulance/rescue squads and other direct patient care facilities. Physician offices performing only waived or PPMP tests and that are owned and/or operated by managed care organizations, hospitals or consulting firms are also included in this group.

Test kits and devices classified as waived are all clearly labeled. A list of tests classified as waived up until January 31, 2000 is available on the CDC website at "www.phppo.cdc.gov/clia/testcat.asp

The FDA assumed the responsibility for classifying the complexity status of laboratory tests in January 2000. A list of tests waived from January 31, 2000 to the present is available on the FDA website at www.fda.gov/cdrh/clia/testswaived.html

Currently, a Limited Service Laboratory must register by completing a "Limited Service Laboratory Registration." Facilities that operate multiple sites must complete an application for each site. No permits are being issued or renewed at this time, pending amendments to regulations contained in Parts 58 and 19 of 10 NYCRR. Instead, facilities registering for the performance of limited testing will be sent a letter confirming the registration and CLIA number. Application forms for a Limited Service Laboratory are available on our website at www.wadsworth.org/labcert/clep/Administrative/ChangeForms.htm or may be obtained by calling the Program office at (518) 485-5378.

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33. What are the qualifications for the director of a Limited Service Laboratory?

A limited service laboratory must have a director who holds an appropriate certificate of qualification (CQ) for the testing performed or a physician, dentist or mid-level practitioner, e.g., physician assistants and nurse practitioners, as defined by CLIA with experience in laboratory testing performed at that facility.

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34. If the provider does not perform the Provider Performed Microscopy Procedures (PPMP), how does that affect test categorization?

If an employee other than a physician, dentist or mid-level practitioner performs a test that is categorized by CLIA as PPMP, the test is classified as moderate complexity and a comprehensive laboratory permit is required.

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35. Why is a laboratory required to obtain a CLIA number? Why is a separate CLIA number required for each site where a facility performs testing?

A CLIA number is required by federal regulation and is issued to a specific site. There are some exceptions to the site specific requirement that take into consideration issues such as ownership and the types and volume of tests performed.

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36. What is an Article 28 facility?

An Article 28 facility is a healthcare facility under the authority of Article 28 of the Public Health Law. Facilities included under the authority of Article 28 are hospitals and related facilities, including private and public institutions, serving as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health related service. Examples of Article 28 facilities include hospitals, nursing homes, and diagnostic and treatment centers.

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Clinical Laboratory Evaluation Program (CLEP)

- Questions or comments related to the Frequently Asked Questions can be directed to CLEP@health.state.ny.us
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